

*AMENDMENT AND RESPONSE TO FINAL OFFICE ACTION*

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**REMARKS**

The present application is directed to methods, devices, and kits for the detection and concentration or isolation of an analyte. In particular, the application relates to the concentration of an analyte using an assay such as an immunoassay to facilitate confirmation of a positive assay result.

Claims 1-20 are pending. Claims 1 and 5-10 are currently amended. New claims 14-25 are added. Favorable consideration of the currently pending claims is respectfully requested in light of the following amendments and remarks. No new matter is added and support for the amendments may be found throughout the specification and original claims.

***Claim rejections under 35 U.S.C. §112, second paragraph***

In the Final Office Action mailed December 8, 2004, the Examiner rejected Claims 8 and 11-13 under 35 U.S.C. §112 as being indefinite for failing to particle point out and distinctly claim the subject matter which applicant regards as the invention. Applicant respectfully submits that the amended Claims overcome the Examiner's rejection.

Applicant has amended Claim 8 to read as an independent Claim. Claim 8 now defines a method for concentrating or isolating a substance. Furthermore, Claim 8 is amended herein to recite the transitional language "consisting essentially of" which limits the steps to the processes recited, and excludes process steps that would have a material affect on the method as claimed. Applicant respectfully submits that amended Claim 8 is now definite. Claims 11-13 depend from amended Claim 8 and thus the rejection is now moot. Applicant respectfully submits they have overcome the rejection under 35 U.S.C. §112 and request the withdrawal thereof.

***Claim rejections under 35 U.S.C. §102(b)***

In the Office Action mailed December 8, 2004, the Examiner rejected Claims 9 and 10 under 35 U.S.C. §102(b) as being anticipated by U.S. Patent No. 5,900,379 to Noda *et al.* The Examiner stated that Claims 9 and 10 are directed to a kit comprising a device wherein a

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portion of the device comprises an immobilized binding partner for the analyte. The Examiner concluded Noda teaches such a device.

Applicant respectfully submits that the amended Claims overcome the Examiner's rejection. Noda *et al.* teach that a first absorbent material, a second absorbent material, or both may be removed from the cassette (see column 4, lines 9-11 and claim 15). The first absorbent material and second absorbent material fail to contain bound analyte material or immobilized binding partner. The analyte is bound to the immobilized binding partner and is therefore retained in the membrane immunoassay portion of the cassette. Applicants respectfully submit that Noda *et al.* fail to teach or suggest the removal or isolation of the **membrane immunoassay** (the portion containing the bound analyte and immobilized binding partner) from the cassette (the device).

The claims of the present application have been amended to clarify that the portion of the device containing the bound analyte and immobilized binding partner (the detection zone) is separated or separable from the remainder of the device. Furthermore, that the portion of the device containing the bound analyte and immobilized binding partner (the detection zone) is separated or separable from the remainder of the device and analyzed to provide information regarding the suspected analyte. Support for this amendment can be found on, at least, page 3, line 35-page 4, line 2; page 11, lines 11-33; and page 15, lines 11-16.

Applicant respectfully submits that Noda *et al.* fail to teach or suggest removal and analysis of the portion of the device containing the bound analyte and immobilized binding partner from the remainder of the device as claimed in the present application. Accordingly, Applicants respectfully request withdrawal of the rejection under 35 U.S.C. §102(b).

In the Office Action mailed December 8, 2004, the Examiner rejected Claims 1-6 under 35 U.S.C. §102(b) as being anticipated by Mazar *et al.* (U.S. Patent No. 6,277,818). The Examiner states that Mazar *et al.* disclose a method for isolating or enriching uPAR-expressing cells from a cell mixture by contacting the cell mixture with a binding compound that is bound to a solid support such as a resin, flat sheet, test strip, etc. and **separating cells**

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from the ligand, thereby enriching or isolating the cells. The Examiner further states that Mazar *et al.* also disclose further enriching the cells by plating and growing them in an appropriate medium.

Applicant respectfully submits that the amended Claims overcome the Examiner's rejection. Claims 1-7 of the instant application are amended herein to reflect that the portion of the device containing the bound analyte is formed as a result of the analyte binding to the immobilized binding partner. The portion containing the bound analyte, or a portion thereof, is then separated from the reminder of the device. The separated portion "containing the bound analyte" will, by default, also contain "immobilized binding partner". The separated portion (containing both the bound analyte and immobilized binding partner) is then further analyzed to provide information regarding the suspected analyte, without detachment from the immobilized binding partner. Support for this amendment can be found on, at least, page 3, line 35-page 4, line 2; page 11, lines 11-33; and page 15, lines 11-16.

In contrast, Mazar *et al.* teach a method for isolating or enriching uPAR-expressing cells from a cell mixture by contacting the cell mixture with the uPAR-binding ligand compound (cyclic peptide); allowing uPAR expressing cells to bind to the compound (that is bound to a solid support such as a resin, flat sheet, test strip, etc); separating cells bound to the ligand from unbound cells (e.g. lateral flow movement of sample through test-strip); and **removing the bound cells from the ligand**, thereby isolating or enriching the uPAR expressing cells.

As stated above, regarding Claims 1-7, the portion of the device containing bound analyte and immobilized binding partner is separated from the reminder of the device without detachment from the immobilized binding partner. Therefore, applicant asserts that Mazar *et al.* fail to teach or suggest the claimed method. Accordingly, Applicants respectfully request withdrawal of the rejection under 35 U.S.C. §102(b).

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***Claim rejections under 35 U.S.C. §102(e)***

In the Office Action mailed December 8, 2004, the Examiner rejected Claims 1-4 and 7-10 under 35 U.S.C. §102(e) as being anticipated by *LaBorde* (U.S. Patent No. 6,607,922). The Examiner states that *LaBorde* discloses an immunochromatographic assay using superparamagnetic beads or particles coupled with antibodies to capture analyte in a sample. The particles are disposed on a test strip that can be removed from a support member for archival or analysis. The Examiner concludes that even though *LaBorde* does not specifically teach a test kit comprising such a device, *LaBorde* anticipates the claims of the present application.

Applicant respectfully submits that the amended Claims overcome the Examiner's rejection. *LaBorde* teaches an immunochromatographic assay **method** that relates broadly to lateral flow devices employing superparamagnetic particles as labels for the analyte to be detected. The bound complexes are captured in a predetermined area of the porous analytical membrane termed the "capture region" or "capture zone" (see column 3, line 1; and element 14 of the drawings). The lateral flow **device** of *LaBorde* contains: an assay support member (element 11 of drawings); a sample receiving element (element 17 of drawings); an immunoassay test strip containing a porous analytical membrane (element 13 of the drawings); at least one **capture region** (element 14 of the drawings); a backing member (element 12 of drawings); and a protective member (element 15 of drawings) with at least one magnetic standard line printed on the protective membrane (element 16 of the drawings). The Examiner states *LaBorde* anticipates the instant claims because the pending claims recite removal of the portion containing bound analyte from at least *a part of the device*. The Examiner concluded that removing the test strip from the housing meets the limitation of "a part of the device".

Applicants respectfully submit that, upon review of *LaBorde*, it can be clearly seen and understood from the text (see Figure 5: test strip removal), that the method of removing the "test strip" requires pealing the entire test strip from the housing, not separating the

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portion of the test strip containing the immobilized binding partner and the bound analyte (the capture region) from the remainder of the test strip as claimed herein.

Claim 8 is amended herein to recite the transitional language “consisting essentially of”, which limits the steps to the processes recited, and excludes method steps that would have a material affect on the method as claimed. Furthermore, Applicant respectfully submits that the amended claims specify the portion of the device containing the bound analyte and the immobilized binding partner (i.e. corresponding to element 14 of *LaBorde*) is separated from the remainder of the device, and that the separated portion is analyzed to provide information regarding the suspected analyte. Applicant respectfully submits that the method claims as provided herein are not taught or suggested by *LaBorde*.

Furthermore, applicant respectfully submits that the device and kit as claimed herein is not taught or suggested by *LaBorde*. The prior art fail to teach or suggest a device comprising structural features that facilitate separation of the capture region containing the bound analyte and the immobilized binding partner or a part of the capture region containing the bound analyte and the immobilized binding partner from the remainder of the device as instantly claimed. Indeed, *LaBorde* suggest the removal and analysis of the entire test strip and not a portion thereof (See column 5, lines 47-59 and Figure 5).

For at least the above reasons, applicant asserts that *LaBorde* fails to teach the claimed device, kit or method. Accordingly, applicant respectfully request withdrawal of the rejection under 35 U.S.C. §102(e).

**CONCLUSION**

Based upon the amendments and remarks provided above, applicant believes that Claims 1-20 are in condition for allowance. A Notice of Allowance is therefore respectfully solicited.

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No additional fees are believed due; however, the Commissioner is hereby authorized to charge any additional fees that may be required, or credit any overpayment, to Deposit Account No. 11-0855.

If the Examiner believes any informalities remain in the application that may be corrected by Examiner's Amendment, or there are any other issues that can be resolved by telephone interview, a telephone call to the undersigned attorney at (404) 815-6500 is respectfully solicited.

Respectfully submitted,



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